REMARKS

Reconsideration is requested of the rejection of claims 1-20 under 35 U.S.C. 112, first paragraph, for lack of enablement.

Applicant respectfully submits that the specification enables the invention, as claimed. The Examiner has not cited any deficiency in the disclosure as such, but points to the fact that hydrocortisone[1] is the only corticosteroid provided in the examples, that the examples employ calamine as a lotion rather than as an ingredient in the composition, that clotrimzole is the only imidazole anti-fungal used in the examples, and that "one does not know if high potency corticosteroids would yield and adverse effect when combined with calamine lotion and clotrimazole." Office action at page 4. Such observations, however, are insufficient to support an enablement rejection. In *Marzocchi*, 169 USPQ 367 (CCPA 1971), the court held that:

> "it is incumbent on the Patent Office whenever a rejection [for enablement] is made, to explain why it doubts the truth or accuracy of any statement in the supporting disclosure and to back up such assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement."[2]

The Office has failed to articulate any reason to doubt the truth or accuracy of any statement. Stated differently, there is no data in applicant's specification nor has the Office pointed to any extrinsic evidence which would cause a person of ordinary skill to to question enablement.

In addition, the Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Factors to consider when determining whether experimentation is "undue" include, but are not limited to:

[1] In the Office action, the Examiner incorrectly identified hydrocortisone as a mid-potency corticosteroid. In fact, it is a low-potency corticosteroid.
[2] 169 USPQ at p. 370

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.[3]

In this instance, the issue is not whether some experimentation would be required, but rather, whether any such experimentation is "undue." The Office does not and, indeed, cannot maintain that undue experimentation would be required to prepare a gel for topical use. Nor can the Office maintain that undue experimentation would be required to determine dosage: applicant provided this information for each of the ingredients, each of which has long been used topically. The only issue raised by the Office is whether an adverse effect would result from the combination; this, however, can be readily determined by experimentation of the type routinely carried out by those of ordinary skill to determine safety.

Finally, the claims are not of equal scope. Some are more specific than others. But yet, the Office has not separately addressed enablement for each of the claims. According to MPEP 2164.08,

> "[a]ll questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims."

[3] *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement).

To support an enablement rejection of each of the claims, therefore, the Office must separately examine the claims. With all due respect, it is submitted that such an analysis would lead to a conclusion of enablement of each of the pending claims.

The Office has rejected each of the pending claims for obviousness-type double patenting. Applicant will consider filing a terminal disclaimer to obviate these rejections in the event the claims are otherwise found to be allowable.

Being filed contemporaneously with this letter is an information disclosure statement. The references cited therein were also cited in applicant's copending application, serial no. 11/123,586. The claims of that application have been finally rejected under 35 USC 112 and 103. Claim 1 of that application reads as follows:

> 1. A process for treating contact dermatitis, the process comprising topically applying a composition to the affected area, the composition comprising (a) a corticosteroid, (b) calamine, and (c) water.

Applicant has filed a notice of appeal.

CONCLUSION

Included with this response is a payment of $405.00 ($225.00 for a two-month extension of time and $180.00 for the filing of the Information Disclosure Statement). The Commissioner is hereby authorized to charge any other fee deficiency or credit any overpayment in connection with this letter to Deposit Account No. 19-1345.

Respectfully submitted,

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EJH/dep